Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re CELGENE CORPORATION SECURITIES LITIGATION	Civil Action No. 18-4772 **OPINION**

John Michael Vazquez, U.S.D.J.

This putative class action alleges securities fraud. Lead Plaintiff AMF Pensionsforsakring, AB ("AMF" or "Plaintiff") asserts that Celgene Corporation ("Celgene") and several of its key officers and/or employees engaged in fraud under Section 10(b) and Rule 10b-5, as well as Section 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78a *et seq.*, as to public statements relating to three drugs in Celgene's new product pipeline. D.E. 57. AMF purchased or acquired Celgene common stock at allegedly artificially inflated prices between January 12, 2015 and April 27, 2018 (the "Class Period"). Currently pending before the Court is Defendants' motion to dismiss Plaintiff's Second Amended Consolidated Class Action Complaint ("SAC") for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), as well as the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u *et seq.* D.E. 52. The Court reviewed the parties' submissions in support and in opposition[1] and decided the

[1] Defendants' moving brief will be referred to as "Def. Br.," D.E. 54; Plaintiff's opposition will be referred to as "Plf. Opp," D.E. 70; Defendants' reply will be referred to as "Def. Reply," D.E. 71. Plaintiff also submitted a notice of supplemental authority on August 5, 2019, D.E. 72, to which Defendants responded, D.E. 73.

motion without oral argument pursuant to Fed. R. Civ. P. 78(b) and L. Civ. R. 78.1(b). For the reasons stated below, Defendants' motion to dismiss is granted in part and denied in part.

I. INTRODUCTION[2]

A. Background

Celgene is a biopharmaceutical company that primarily develops and commercializes drugs for the treatment of cancer and inflammatory diseases. SAC ¶ 64. During the Class Period, Defendant Mark J. Alles was the Chief Executive Officer ("CEO") of Celgene. *Id.* ¶ 66. Defendant Robert J. Hugin was most recently, the Executive Chairman of Celgene's Board of Directors from March 1, 2016 until February 5, 2018. *Id.* ¶ 67. Defendant Scott A. Smith served as Celgene's President and Chief Operating Officer ("COO") from April 1, 2017 until April 2, 2018. Prior to April 1, 2017, Smith was President of Celgene's Inflammatory & Immunology ("I&I") franchise. *Id.* ¶ 68. Defendant Peter N. Kellogg was Celgene's Chief Financial Officer ("CFO") and Chief Accounting Officer ("CAO") during the Class Period. *Id.* ¶ 69. From April 2013 until March 2016, Defendant Terrie Curran was Celgene's U.S. Commercial Head of the I&I franchise. From March 2016 through April 2017, Curran was Head of Worldwide Markets for Celgene's I&I Franchise and was promoted to President of the Global I&I franchise on April 1, 2017. *Id.* ¶ 70. Defendant Jacqualyn A. Fouse was the Strategic Advisor to the Celgene Management Executive Committee from April 1, 2017 to June 30, 2017. From March 2016 to March 2017, Fouse was President and COO of Celgene. Fouse retired in June 2017. *Id.* ¶ 71.

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[2] The facts are derived from Plaintiff's SAC. D.E. 57. When reviewing a Rule 12(b)(6) motion to dismiss, the Court accepts as true all well-pleaded facts in the complaint. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). Additionally, a district court may consider "exhibits attached to the complaint and matters of public record," as well as "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

Defendant Philippe Martin has been Celgene's Vice President of Leadership & Project Management – Immunology since January 2014. From June 2016 to June 2018, Martin also served as the Managing Director of Receptos. *Id.* ¶ 72. Defendant Nadim Ahmed worked in multiple positions in Celgene's Hematology & Oncology franchise during the Class Period including President, President of Worldwide Markets for Hematology & Oncology, and General Manager for U.S. Hematology & Oncology. *Id.* ¶ 73. Defendant Jonathan Q. Tran is currently the Executive Director of Clinical Pharmacology at Receptos, which was acquired by Celgene in July 2015. *Id.* ¶ 74. Defendant Peter Callegari, M.D., is Corporate Vice President of Global Medical Affairs for Celgene's I&I franchise. *Id.* ¶ 75.

Celgene manufacturers and sells the multiple myeloma drug Revlimid, which in 2010, accounted for approximately seventy percent of Celgene's total annual product sales. *Id.* ¶ 99. Revlimid's patent expires in 2022. *Id.* ¶ 101. Because of the looming expiration of the Revlimid patent, "Celgene was under intense pressure . . . to create and maintain a drug pipeline . . . to offset the anticipated loss in revenues that would result from generic Revlimid competitors entering the market." *Id.* Defendants do not appear to dispute these facts. What Defendants deny, however, are Plaintiff's allegation that Defendants committed securities fraud with respect to statements about three products in the I&I franchise that Celgene was developing as potential Revlimid revenue replacements. The I&I products at issue are (1) GED-0301, (2) Otezla, and (3) Ozanimod. Each product is discussed in turn. The Court addresses the specific allegations below.

1. GED-0301

In 2014, Celgene entered into a license agreement with Nogra Pharma Limited ("Nogra"), a private pharmaceutical company in Ireland, to develop and commercialize GED-0301. Celgene initially paid Nogra $710 million, which at the time, was the largest upfront payment by a drug

company to acquire a single drug. *Id.* ¶ 108. GED-0301 is an oral medication used to treat inflammatory bowel disease ("IBD").[3] *Id.* ¶¶ 105, 07-08. The two primary treatments currently on the market for IBD are "biologic" therapies. Both are only administered through injection, carry an increased risk of infection, and are not effective for as many as one-third of IBD patients. *Id.* ¶ 106. According to Celgene, GED-0301, which is not a biologic, "offered a potential new path to break into the lucrative IBD market." *Id.* ¶ 107.

In an April 2014 press release announcing the license agreement, Celgene described GED-0301 as a "late-stage product" and explained that a placebo-controlled Phase II[4] study was complete. *Id.* ¶ 111. The press release stated that "GED-0301 is a potentially transformative therapy that demonstrated striking clinical activity in a phase II trial for Crohn's disease." *Id.* ¶ 112. The press release continued that based on the Phase II data that Celgene reviewed during its pre-acquisition diligence, Celgene intended to begin recruiting patients for a Phase III clinical trial. *Id.* ¶ 111. Certain Defendants made similar statements during an investor call that same day and

[3] IBD is a term used to describe two similar disorders, Crohn's disease ("CD") and ulcerative colitis ("UC"), which both involve chronic inflammation of the digestive tract. SAC ¶ 105. "[A]n estimated 3.1 million people in the U.S. were diagnosed either with CD or UC in 2015." *Id.*

[4] "Clinical trials are a kind of clinical research designed to evaluate and test new interventions such as psychotherapy or medications." *What Are the Different Types of Clinical Research?*, FDA.gov, https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research (Jan. 4, 2018). With respect to clinical trials for drug development and FDA approval, the trials are usually conducted in four phases, with the first three phases occurring before FDA approval. Generally, Phase I trials utilize a small group of people and researchers evaluate the drug's safety and proper dosage. Phase II trials are larger and are used to see if the drug is an effective treatment. For a Phase III clinical trial, the drug is given to large groups of people so researchers can confirm effectiveness, safety, monitor side effects and compare it to commonly used treatments. Finally, Phase IV trials are post-marketing studies, after the drug is approved by the FDA and provide additional information about the drug's risk, benefits, and best uses. *Id.*

in further discussions with analysts. *Id.* ¶¶ 113-14. At the time, the only publicly available data about GED-0301 was a 15-person Phase I trial. *Id.* ¶ 110.

Plaintiff alleges, however, that Defendants' statements as to the potential for GED-0301 were not supported by the existing scientific data. Relying on statements from anonymous former Celgene employees, consultants, and scientists ("FEs"), Plaintiff pleads that Defendants knew there was a lack of evidence demonstrating that GED-0301 was an effective treatment for IBD when Celgene entered into the license agreement with Nogra. *Id.* ¶ 118. Plaintiff focuses on the fact that the Phase II clinical results "lacked endoscopic evidence of efficacy," *id.* ¶ 119, and that Celgene knew this was a shortcoming of the Phase II data. *Id.* ¶¶ 119-28. The Phase II study relied on the Crohn's Disease Activity Index ("CDAI"), which measures the severity of symptoms as reported by patients. *Id.* ¶ 119. The CDAI, by its very nature, is a subjective measurement. Endoscopic evidence, by comparison, provides an objective measurement because it confirms the existence of ulcers in patients at both the beginning and end of the study. *Id.*

On March 18, 2015, the Phase II study results were published in the *New England Journal of Medicine* ("NEJM"). *Id.* ¶ 137. Celgene also issued a press release on March 18, 2015 stating, among other things, that GED-0301 "has the potential to transform the Crohn's treatment landscape" and that Celgene was planning to move forward with a Phase III trial. *Id.* An editorial in the same NEJM issue questioned the findings of the Phase II study, in part, because of the lack of endoscopic evidence. *Id.* ¶¶ 138-39. FE 1[5] states that Celgene's GED-0301 Advisory Board discussed the limitations identified in the editorial, including the lack of endoscopic evidence. *Id.* ¶ 140. According to FE 1, the Advisory Board agreed with the identified limitations, that this view

[5] FE I is an "IBD and clinical trials expert who previously served as a consultant to Celgene" with respect to Celgene's acquisition of GED-0301 and assisted in planning Celgene's GED-0301 clinical trials. SAC ¶ 77.

was communicated to Celgene, and that Celgene "acknowledged the limitations" of the Phase II data. *Id.* ¶¶ 141, 154. Publicly, Celgene continued to put a positive spin on the clinical data and stated that Celgene would provide evidence demonstrating that GED-0301 was a promising treatment through Phase Ib study data. *Id.* ¶¶ 143-53. The Phase 1b study would include endoscopy data. *Id.* ¶ 145.

On September 12, 2016, Celgene released initial results from the Phase Ib study. The Company issued a press release, and Smith stated at a conference, that endoscopic data from the study indicated improvements in patients that used GED-0301. *Id.* ¶¶ 157-58. Celgene reported the full interim Phase Ib study results in an October 16, 2016 press release. *Id.* ¶ 159. In the October 16 press release, Smith stated that the study showed "both meaningful endoscopic improvement and clinical remission at an early time point in this study." *Id.* Callegari reiterated this information in an October 18, 2016 conference call. On the same call, Celgene represented that the "only open issue concerning GED-0301's efficacy was whether the drug caused 'long-term endoscopic remission,' which was being tested in the ongoing Phase III 'Revolve' trial." *Id.* ¶ 161. Smith also stated that Celgene was on track to submit GED-0301 for FDA approval in 2018. *Id.* ¶ 162.

Plaintiff alleges that internally Celgene recognized the limitations of the Phase Ib data because the study was conducted without a placebo or acceptable alternative control. *Id.* ¶ 164. FE 1 explains that the failure to include a placebo control arm was a "corporate decision." *Id.* ¶ 167. FE 1 voiced his concerns about the structure of the Phase Ib study with numerous individuals, including Celgene employees, *id.* ¶ 169, and that Celgene "was consistently advised about the

limited evidence of efficacy," *id.* ¶ 170. FE 4[6] similarly states that evidence regarding GED-0301's efficacy was a "hot topic" at Celgene, and that "it was known internally . . . that the lack of a control arm in the phase Ib trial meant that the results did not support Celgene's claims regarding GED-0301's efficacy." *Id.* ¶ 173. Externally, analysts also noted that the lack of a control group "raised questions about the ability to draw conclusions" from the study results. *Id.* ¶¶ 179-82. Defendants' statements, in particular from Smith, appeared to mollify analysts and investors. *Id.* ¶ 183.

The Phase III trial started on December 8, 2015 and was expected to take at least two years to complete. In what appears to be a direct response to earlier criticisms, the Phase III trial used endoscopic measurements and had a placebo arm. *Id.* ¶ 184. As the Phase III trial progressed, Defendants assured investors that the Company was "on-track" with respect to GED-0301's launch. *Id.* ¶ 185. But Plaintiff alleges that there was "significant concern" that GED-0301 would not make it past the Phase III clinical trial. *Id.* ¶ 187. In fact, according to FE 4, Celgene had effectively given up on GED-0301 after the Phase Ib study.

Plaintiff relies on the following to establish that Celgene had internally "given up" on GED-0301. As of the spring of 2017, FE 4 does not recall GED-0301 being discussed in any of the quarterly review meetings with Celgene's Vice Presidents, which was "unusual." *Id.* In addition, FE 5[7] recalls that during a meeting in the spring of 2017, there was a "focus[] on how

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[6] FE 4 is a Celgene employee who worked with the design, implementation, and analysis of certain aspects of Celgene's clinical Phase I and Phase II trials and was also "a member of the research management team where he oversaw the research and development for Celgene's developmental drugs." SAC ¶ 80.

[7] FE 5 was a Director at Receptos from mid-2015 to mid-2017 who was involved with the Ozanimod studies. Due to his role, FE 5 "was a regular attendee at meetings related to Celgene's Ozanimod clinical trials" and he reviewed the GED-0301 Phase Ib results "in connection with his work on Ozanimod." SAC ¶ 81.

Ozanimod needed to become a first line therapy for CD." *Id.* ¶ 188. FE 5 believes this was significant given Celgene's public representation that GED-0301 was the Company's CD treatment. *Id.* Moreover, at other meetings, Defendant Martin and other Celgene employees were pushing the Ozanimod CD team to show better efficacy than GED-0301, including by manipulating the Ozanimod testing data. *Id.* ¶¶ 188-91. In July 2017, FE 4 states that a non-party employee, Horan, told FE 4 that the Phase III trial was going to be "scrapped." *Id.* ¶ 61. FE 4 "believes" that Horan was in a position to access Phase III data while the study was on-going, which could then be "extrapolated to determine whether GED-0301 was having the desired effect." *Id.* ¶ 193. FE 6[8] also states that he was informed by a Celgene colleague in August 2017 that the Phase III trial would be discontinued. According to FE 6, during a meeting that was attended by the unnamed colleague, Callegari and Diamond, "the participants discussed the fact that the GED-0301 Phase III trial would not be successful." *Id.* ¶ 194. FE 6 does not state that the meeting participants explicitly discussed terminating the Phase III trial early.

Despite Plaintiff's allegations that Celgene had internally "given up" on GED-0301, Defendants continued to make public statements about GED-0301's efficacy and Celgene's anticipated market launch. For example, during a July 2017 conference call, Curran stated, among other things, that "progress continues with GED-0301." *Id.* ¶ 195. At conferences in September 2017, Celgene's presentation included a slide that listed 2019 as the year for potential FDA approval for GED-0301. *Id.* ¶¶ 196-97. Moreover, at a conference in September 2017, Alles stated that Celgene expected regulatory approval for GED-0301 in 2019. *Id.* ¶ 198.

[8] FE 6 was a Regional Medical Liaison for Celgene's I&I franchise in the New England region. FE 6 worked with account manager teams "to identify scientific and medical support needs for accounts with marketed and pipeline products." SAC ¶ 82. GED-0301 was part of the I&I portfolio. *Id.* ¶ 9.

Celgene continued with the Phase III trial until announcing on October 19, 2017 that it was discontinuing the trial. *Id.* ¶ 200. In a Form 8-K, Celgene stated that it would recognize a $1.6 billion fourth quarter charge to earnings as a result of the decision to end the trial. After this announcement, Celgene common stock declined approximately 11%, from $135.96 per share on October 19, 2017 to $121.33 per share on October 20, 2017. *Id.* ¶ 202. Celgene has not issued any further press releases on GED-0301, and analysts have stated that for all practical purposes, GED-0301 is dead. *Id.* ¶ 204.

2. Otezla

Otezla is "an oral medication that is used to treat [psoriatic arthritis ("PA")] and psoriasis."[9] *Id.* ¶ 205. Months before the Otezla launch, "Defendants primed the market that Otezla sales were poised to sky-rocket, representing that Otezla net product sales would reach $1.5 billion to $2 billion by 2017." *Id.* ¶ 206. Otezla was approved by the FDA for the treatment of PA in March 2014, and Celgene first recognized revenue from Otezla sales during the second quarter of 2014. *Id.*

In a January 12, 2015 press release, Celgene set out its five-year strategic growth plan, which included a projection that Otezla sales in 2017 would range between $1.5 and $2 billion. During a presentation the same day, Hugin highlighted the 2017 projection and claimed that the fourth quarter 2014 sales numbers for Otezla give "us great confidence that we are on track to really again meet or exceed the 2017 guidance." *Id.* ¶ 207. Plaintiff alleges that Defendants lacked a reasonable basis for these statements because as early as 2014, Otezla's sales "were severely impaired by several dynamics." *Id.* ¶ 210.

[9] Psoriasis is a chronic skin condition that causes extra skin cells to build up on the surface of the skin in scales and red patches, which are itchy and sometimes painful. Psoriatic arthritis is a type of arthritis that affects some people with psoriasis. SAC ¶ 205 n. 11.

First, FE 7[10] explained that shortly after the Otezla launch, Celgene offered excessive rebates and discounts to convince insurance companies to remove "step-edits." *Id.* ¶ 211. Step-edits are put in place by insurers and pharmacy benefit managers ("PBMs"), and require patients to try less expensive medications before being approved to use a more expensive medication. *Id.* But according to FE 7, rather than boosting net sales by capturing market share, Celgene's "pay-to-play" pricing plan drove the market price for Otezla down. This "ensur[ed] that [Celgene] would never meet the 2017 Otezla net sales guidance." *Id.* ¶ 212. In fact, FE 7 "repeatedly warned" Smith and other senior executive managers that Celgene's strategy was "fatally flawed" and "would not work to increase revenues." *Id.* ¶¶ 214-15. FE 7 reports that in response, Smith told him that Celgene would do "whatever it takes to get the business." *Id.* ¶ 214. FE 7 also reported that Otezla was an inferior product to its competition. *Id.* ¶ 216. This belief was echoed by additional FEs. *Id.* ¶ 221. Moreover, there were multiple competitors to Otezla, many of which had been on the market for years and were "well-accepted by physicians." *Id.* ¶ 222. In addition, according to FE7, Smith hired an inexperienced Otezla sales team, *id.* ¶¶ 217, 224, and sales were flat in 2015, 2016, and 2017, *id.* ¶ 218. Celgene's management team allegedly had access to this sales data. *Id.* ¶ 219. Finally, Celgene faced difficulties in bringing Otezla to the European market. *Id.* ¶¶ 225-30. Plaintiff alleges that these impediments "rendered Celgene's 2017 Otezla [sales] guidance unattainable." *Id.* ¶ 220.

Throughout 2015 and 2016, Defendants represented that Celgene was on-track to meet the 2017 sales projection. *Id.* ¶¶ 231-33. As early as July 2016, however, Defendants purportedly

[10] FE 7 was a Senior National Account Manager at Celgene from 2013 to 2016. FE 7 advised Curran and non-party senior executives on the pricing and market access strategies for Otezla.

received explicit warnings that the 2017 projection was unattainable. *Id.* ¶ 234. FE 17[11] explains that there was no growth in Otezla sales by 2016, and that the lack of growth and reasons for lack of growth were "expressly communicated" to Defendants Smith and Curran by no later than the third quarter of 2016. *Id.* ¶ 235. FE 17 informed the I&I Executive Committee ("IIEC") , which included Smith and Curran, of this information during detailed presentations in the third and fourth quarters of 2016. At one of the meetings during the fourth quarter, FE 17 explicitly advised the IIEC that the sale guidance needed to be lowered. According to FE 17, non-party Robert Tessarolo, the Senior Vice President of I&I, told the IIEC the same thing, but the IIEC "insisted that the guidance would not be changed." *Id.* ¶ 237. FE 17 also states that Tessarolo provided the same warnings in weekly IIEC meetings throughout the same time period. *Id.* ¶ 236. In response, Defendants "put pressure on the salespeople to hit the impossible numbers." *Id.* ¶ 241.

Publicly, Defendants continued to reaffirm the 2017 target. At a September 12, 2016 conference, Smith stated that "Otezla is moving along very nicely" and that he "feel[s] really great about where we are going and the numbers both in 2017 and 2020 that we put out there." *Id.* ¶ 242. On an October 27, 2016 conference call, Smith "expressed a 'high degree of confidence' in Celgene's ability to meet the 2017 Otezla sales guidance." *Id.* ¶ 242.

But in a January 9, 2017 Form 8-K, Celgene lowered the top end of the projection from $2 billion to $1.7 billion. The press release stated that this would represent a 57% year-over-year growth for Otezla. *Id.* ¶ 244. Again, multiple FEs confirmed that the statement about 57% year-over-year growth was unattainable given the problems identified above. *Id.* ¶ 246. In addition, according to FE 17, by April 2016 "managed care was 'underwater'" and new prescriptions and

[11] FE 17 was a senior executive in Celgene's U.S. Market Access group from early 2016 to late 2017, and he "worked with the managed care team where he negotiated new contracts with health plans." SAC ¶ 93.

patients were down. *Id.* ¶ 247. Managed care was "underwater" because when Celgene entered into a new PBM contract that required rebates, Celgene was responsible for paying rebates on all new and existing prescriptions. *Id.* ¶ 248. "As early as April 2016, the rebates due on existing Otezla prescriptions covered by these 'underwater' contracts were 'significant' and amounted to millions of dollars." *Id.* Moreover, in late 2016, Celgene allowed wholesalers to buy in excess of their demand at reduced prices, in anticipation of a price increase that was planned for 2017. *Id.* ¶¶ 247, 249. According to FE 7 and FE 17, Smith and the IIEC were again informed that Celgene was unlikely to meet the 2017 Otezla sales target. *Id.* ¶¶ 250-52.

On April 27, 2017, Celgene announced that its Otezla net product sales did not meet the Company's expectations, "with just a 14% year-over-year increase and a 1% decline in sales." *Id.* ¶ 253. Celgene reaffirmed its forecasted 57% year-over-year growth, "stating that the 'Updated 2017 Guidance' for Otezla was 'Unchanged.'" *Id.* During a conference call on April 27, Kellogg "reassure[ed] investors that the new PBM contracts and elimination of step-edits would improve market access, and by extension, Otezla net product sales for 2017." *Id.* ¶ 254. Plaintiff alleges that Defendants had no reasonable basis for making these representations. *Id.* ¶ 255.

Plaintiff maintains that the removal of step-edits for certain new PBM contracts was not enough to overcome the already discussed hurdles, of which Defendants were aware. *Id.* ¶ 256. During meetings in November or December 2016, FE 7 warned Curran and other non-party executives that paying to remove step-edits "was not a cure for the drug's broad-based market access challenges." *Id.* ¶ 257. And although Celgene was able to remove step-edits for some contracts, FE 7 believed that it "was too little too late and could not spur on Otezla sales enough to close the widening gap between the actual Otezla sales and the Company's knowingly unreasonable 2017 guidance." *Id.* ¶ 258. Moreover, many of the new PBM contracts that Celgene

entered into in 2017 took several months to generate revenues. *Id.* ¶ 259. FE 18[12] explained that "based on the models that his team was running monthly," it was clear from the beginning of 2017 that the new PBM contracts were not meeting revenue expectations. *Id.* ¶ 261. FE 18 believes that this information was reported to the Corporate Pricing & Market Access Committee. *Id.* Eventually, Celgene "internally lowered the expectations on many of these PBM contracts" according to Plaintiff. *Id.* ¶ 262. This information was not publicly disclosed until the end of the third quarter of 2017.

On October 26, 2017, Celgene "stunned the market by announcing that, in light of the dismal Otezla sales numbers, the Company had slashed the 2017 guidance by more than $250 million" and lowered the 2020 I&I guidance by over $1 million. *Id.* ¶ 264. During the corresponding third quarter conference call, Alles attempted to blame the drop on slowing growth across the dermatology market. *Id.* ¶ 265. FEs, however, state that this explanation simply was not accurate, and that for the reasons discussed above, the 2017 sales target was unattainable from the start. *Id.* ¶¶ 265-66. After this news was announced, the price of Celgene common stock declined more than 16%; from $119.56 per share on October 25, 2017 to $99.99 per share on October 26, 2017. *Id.* ¶ 269.

3. Ozanimod

Celgene's final I&I pipeline product was Ozanimod, which was initially developed by Receptos to treat relapsing multiple sclerosis ("RMS") and UC. SAC ¶ 270. On July 14, 2015, Celgene purchased Receptos for $7.2 billion. In announcing the acquisition, Celgene "projected annual Ozanimod sales of up to $6 billion." *Id.* ¶ 271. Celgene placed its own personnel at

[12] FE 18 was a senior executive in Celgene's U.S. Health Economics and Outcomes Research group; FE 18 reported to Swartz. SAC ¶ 94.

Receptos' headquarters in San Diego immediately after the acquisition. FE 20[13] explained that, Receptos personnel were thereafter "out of the decision-making loop and important decisions were made by Celgene." *Id.* ¶ 272. Specifically, FE 20 contends that Martin came from Celgene to Receptos to oversee the Ozanimod NDA filing. *Id.* ¶ 273. FE 2[14] and FE 5 both stated that Martin acted like the CEO of Receptos and reported to Smith. *Id.*

Ozanimod was not approved by the FDA when Celgene acquired Receptos. If Ozanimod were to obtain FDA approval, its main competitor would be Gilenya, a drug manufactured by Novartis. *Id.* ¶ 275. Celgene expected to capture the Gilenya market share after it obtained FDA approval because Ozanimod allegedly had a much shorter half-life than Gilenya. Celgene anticipated filing a New Drug Application ("NDA") for Ozanimod with the FDA in 2018. *Id.* ¶¶ 276-79. In 2015, however, the U.S. Patent and Trademark Office unexpectedly quashed Novartis' Gilenya patent claims. As a result, generic competitors to Gilenya were expected to enter the market by the end of 2019. *Id.* ¶ 279. "Thus, despite Ozanimod's purportedly superior half-life and safety profile, the availability of cheaper generic alternatives with a similar efficacy starting in 2019 would make it more difficult for Ozanimod to gain widespread acceptance among RMS patients." *Id.* ¶ 280.

FDA guidance directs companies to "identify all metabolites early on in the drug development process and to conduct extensive safety testing of any active metabolites that are

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[13] FE 20 was a senior executive in Clinical Development at Receptos from before the class period until 2016. FE 20 was responsible for conducting all the Phase II and Phase III studies for Ozanimod in multiple sclerosis ("MS") and UC. SAC ¶ 96.

[14] FE 2 worked in clinical research and development within the I&I franchise from before the class period began through late 2016. FE 2 assisted with "long-term planning of both organizational and project-related activities, . . . participated in clinical development planning for I&I's compounds and managed departmental activities to ensure on-time delivery of the clinical regulatory submissions." SAC ¶ 78.

discovered during the course of these pharmacological analyses." *Id.* ¶ 282. Companies may avoid significant delays in the FDA review and approval process by following this guidance. Metabolites, which refers to products that remain after a drug is broken down by the body, may be "active" or "inactive." *Id.* ¶ 49. Unlike inactive metabolites, "[a]ctive metabolites continue to produce effects in the body after their formation." *Id.* ¶ 282. Moreover, after multiple doses of the drug, active metabolites can accumulate in the body and alter the safety and therapeutic effects of the drug. *Id.* Once identified, certain metabolites require additional testing before FDA approval. Namely, there should be additional metabolite testing in cases where the metabolite is only formed in humans and not in animal test species, or if the metabolite "is present at disproportionately higher levels" in humans than in animals. This additional safety testing should occur before filing an NDA. *Id.* ¶ 289. FDA guidance also provides that there may be additional safety concerns if the human metabolite forms at a "greater than 10 percent of parent drug systemic exposure at steady state." *Id.* "Radiolabeled mass balance studies" test for the presence of metabolites in humans. *Id.* ¶ 288.

When Celgene acquired Receptos, Celgene continued with two on-going Phase III clinical trials that were initiated by Receptos. *Id.* ¶ 281. FE 21[15] stated that Celgene was still undertaking many Phase I studies in 2016 despite the fact that it had been proceeding with large-scale Phase III clinical trials for more than a year. *Id.* ¶ 294. In fact, "[Celgene] delayed administration of the 'gold standard' radiolabeled mass balance study," *id.* ¶ 293, and analysts were not aware that Celgene was performing the clinical trials out of order, *id.* ¶ 296.

[15] FE 21 was a clinical pharmacologist from late 2016 to early 2018 at Receptos and worked on the Phase I studies of Ozanimod. FE 21 had "first-hand knowledge of the Metabolite starting at the time of its discovery" and after the discovery, worked on studies regarding the Metabolite.

On October 17, 2016, Celgene began recruiting subjects for a Phase I trial (the "Mass Balance Study"). *Id.* ¶ 297. Celgene completed the Mass Balance Study on November 21, 2016. Through this study, Celgene identified a metabolite named CC112273 (the "Metabolite") "which triggered the need for the additional testing described in the FDA guidance." *Id.* ¶¶ 51, 297. In fact, the study results "far exceeded the 10% threshold trigger for additional testing set forth in the FDA guidance" and was present at disproportionately higher levels in humans than animal test subjects. *Id.* ¶¶ 300-01. The Mass Balance Study also revealed that the half-life for the Metabolite was significantly longer than Ozanimod's half-life of nineteen hours. *Id.* ¶ 302.

FE 21, who had first-hand knowledge of the Metabolite discovery, reported that his manager, who others have identified as Martin, told him not to tell anyone about the Metabolite. FE 21 "learned that members of Celgene's senior leadership team knew about the discovery of the Metabolite and received updates on the issue." *Id.* ¶ 299. Moreover, according to FE 21 and FE 5, Defendants knew that Celgene needed to conduct additional testing on the Metabolite before filing the NDA. *Id.* ¶¶ 303-04. FE 5 recalled that in March or April of 2017, Tran confirmed the need for additional testing at a meeting that was attended by Martin, among others. *Id.* ¶ 304.

Despite the need for additional testing after discovery of the Metabolite, in a February 10, 2017 annual report and an April 27, 2017 quarterly report, Celgene represented that the Ozanimod development was in Phase III. *Id.* ¶ 307. In addition, Defendants continued to represent that Celgene was on track to submit the NDA before the end of 2017. On January 9, 2017, Alles explained that Celgene expected to have data from two Phase III trials during the first half of the year, and contingent on that data, Celgene would file the NDA by the end of the year. *Id.* Alles failed to mention the Metabolite discovery during this conference.

Celgene received the results from both of the Phase III trials in the spring of 2017 and Defendants continued to represent that Celgene was on track to file the NDA by years' end. *Id.* ¶ 308. In addition, on August 7, 2017, the *Journal of Clinical Pharmacology in Drug Development* published a paper that was authored by Tran and other Celgene employees about Ozanimod. In this paper, Tran stated that three animal metabolites were identified through metabolite studies and described the animal metabolites. The paper did not disclose the Metabolite that was discovered via the Mass Balance Study. *Id.* ¶¶ 310-11. On October 26, 2017, Curran again reiterated that Celgene was on-track to file the NDA by the end of the year. *Id.* ¶ 315.

Celgene employees, however, advised Defendants that Celgene should complete the Metabolite testing before filing the NDA. According to FE 22,[16] "in November 2017, the FDA confirmed that Celgene was required to submit the results of the additional Metabolite testing with its NDA." *Id.* ¶¶ 316-18. Although the additional Metabolite studies were underway, study results were not expected until April 2018. *Id.* ¶ 319. Even after the FDA expressly informed Celgene that it needed to include the Metabolite testing results with its NDA submission, Celgene continued to move forward with its plan to submit the NDA in December 2017 without the Metabolite study results. *Id.* ¶ 318.

Plaintiff alleges that Celgene's decision to move forward with the NDA submission before obtaining the additional Metabolite study results was motivated by two factors. First, Celgene wanted to gain market share for Ozanimod before generic versions of Gilenya entered the market in 2019. *Id.* ¶¶ 320. In addition, many high-ranking Celgene employees, including Martin, would receive bonuses or additional compensation if the NDA was submitted to the FDA by the end of

[16] FE 22 was a contractor for Receptos and worked as a Project Manager for the Ozanimod UC/CD team in San Diego from late 2017 to early 2018. FE 22 oversaw the Ozanimod drug development through various clinical stages during this time period.

2017. *Id.* ¶ 321. Celgene submitted the Ozanimod NDA in December 2017 as planned. *Id.* ¶ 319. After submitting the NDA, Celgene issued a press release on January 8, 2018 stating that it expected an FDA decision on the NDA in 2018. *Id.* ¶ 322.

On February 27, 2018, Celgene disclosed that it received a refuse to file ("RTF") letter from the FDA in response to the Ozanimod NDA submission. "The FDA can refuse to file an NDA and issue an RFT letter if it identifies clear and obvious deficiencies in a company's submission." *Id.* ¶¶ 323-24. According to the FDA's standard operating policy and procedures, an RFT "is based on omissions of clearly necessary information . . . or omissions or inadequacies so severe as to render the application incomplete on its face and where the deficiencies are obvious[.]" *Id.* ¶ 324. An RFT is based on "scientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety, purity and potency or provide adequate directions for use." *Id.* ¶ 325. As a result of the RFT announcement, Celgene's common stock fell from $95.78 per share on February 27, 2018 to $87.12 per share on February 28, 2018. *Id.* ¶ 330. Moreover, Smith "was ushered out of Celgene in April 2018, and Martin was relieved of his responsibilities at Receptos in June 2018. *Id.*

On April 25, 2018, several scientists gave a presentation at a medical conference that disclosed certain aspects of the Metabolite. The presentation was partially sponsored by Celgene. *Id.* ¶ 331. Days after the presentation, the market learned that additional testing on the Metabolite was required, which could delay Celgene's ability to refile the Ozanimod NDA by up to three years. *Id.* ¶ 332. Celgene's common stock then fell from $95.78 per share on April 27, 2018 to $87.10 per share on April 30, 2018. *Id.* During its first quarter conference call on May 4, 2018, Celgene confirmed that the RFT arose because of the Metabolite and that Celgene discovered the Metabolite via the Mass Balance Study in November 2016. *Id.* ¶ 333. When the SAC was filed,

Celgene still had not re-submitted its Ozanimod NDA nor had it received results from the additional Metabolite testing.

B. Procedural History

Plaintiff the City of Warren General Employees' Retirement System filed the initial putative class action complaint in this matter on March 29, 2018. D.E. 1. On May 3, 2018, Plaintiff Charles H. Witchcoff filed a class action complaint asserting similar securities fraud claims against Celgene and certain Celgene executives. By May 29, 2018, ten parties had filed motions to consolidate the cases and appoint a lead plaintiff. D.E. 36. On September 26, 2018, this Court consolidated the two cases; appointed AMF, the presumptive lead plaintiff, as the lead plaintiff; and appointed class counsel. D.E. 36. AMF filed an Amended Complaint on December 10, 2018. D.E. 40. Plaintiff then filed the SAC on February 27, 2019, alleging the following two counts: (i) violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants; and (ii) violations of Section 20(a) of the Exchange Act against Defendants Alles, Kellogg, Smith, Curran, Hugin, and Fouse (the "Section 20(a) Defendants"). D.E. 57. Defendants filed their motion to dismiss on February 8, 2019 and seek to dismiss the SAC in its entirety pursuant to Rule 12(b)(6) and the PSLRA.[17] D.E. 52.

II. LEGAL STANDARD

A. Rule 12(b)(6)

Rule 12(b)(6) permits a defendant to move to dismiss a count for "failure to state a claim upon which relief can be granted[.]" To withstand a motion to dismiss under Rule 12(b)(6), a

[17] The SAC was filed pursuant to Rule 15(a)(1)(B) and omitted partial sentences from three paragraphs of the Amended Complaint. Defendants did not oppose the proposed amendment. D.E. 56 at 1. Moreover, while Plaintiff filed the SAC after Defendants filed the instant motion to dismiss, the parties agreed that the motion to dismiss would apply to the SAC. *See* Feb. 25, 2019 Joint Stipulation, D.E. 56.

plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint is plausible on its face when there is enough factual content "that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although the plausibility standard "does not impose a probability requirement, it does require a pleading to show more than a sheer possibility that a defendant has acted unlawfully." *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 786 (3d Cir. 2016) (internal quotation marks and citations omitted). As a result, a plaintiff must "allege sufficient facts to raise a reasonable expectation that discovery will uncover proof of [his] claims." *Id.* at 789.

In evaluating the sufficiency of a complaint, a district court must accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). A court, however, is "not compelled to accept unwarranted inferences, unsupported conclusions or legal conclusions disguised as factual allegations." *Baraka v. McGreevey*, 481 F.3d 187, 211 (3d Cir. 2007). If, after viewing the allegations in the complaint most favorable to the plaintiff, it appears that no relief could be granted under any set of facts consistent with the allegations, a court may dismiss the complaint for failure to state a claim. *DeFazio v. Leading Edge Recovery Sols., LLC*, No. 10-2945, 2010 WL 5146765, at *1 (D.N.J. Dec. 13, 2010).

B. PSLRA

The PSLRA imposes further pleading requirements. "The PSLRA established heightened pleading requirements for a plaintiff to meet in order to plead a cause of action successfully in class actions alleging securities fraud." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 241 (3d Cir. 2013). The PSLRA "requires that a complaint state with particularity both the facts constituting

the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention to deceive, manipulate, or defraud." *Id.* at 241-42 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007)) (internal quotations omitted). In other words, plaintiffs bringing a claim involving an allegedly false or misleading statement must "(1) 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading,' 15 U.S.C. § 78u-4(b)(1), and (2) 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind,' § 78u-4(b)(2)." *Rahman*, 736 F.3d at 242 (quoting *Tellabs*, 551 U.S. at 321).

Both provisions of the PSLRA pleading standard require that facts be pled "with particularity," echoing the requirement set forth in Federal Rule of Civil Procedure 9(b).[18] *Id.* at 241 n. 3. Although the "PSLRA replaced Fed. R. Civ. P. 9(b) as the applicable pleading standard in private securities class actions," Rule 9(b)'s particularity requirement "is comparable to and effectively subsumed by the requirements" of the PSLRA. *Id.* This standard "requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story." *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009). Section 78u-4(b)(1) also adds the requirement that where "an allegation regarding [a defendant's] statement or omission is made on information or belief," plaintiffs must "state with particularity all facts on which that belief is formed"; that is, they must describe the sources of information with particularity, including "the who, what, when, where and how of the sources, as well as the who, what, when, where, and how of the information those sources convey." *Id.*; *see* 15 U.S.C. § 78u-4(b)(1).

[18] Rule 9(b) provides that when "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake . . . [m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Defendants do not separately move pursuant to Rule 9(b). As a result, the rule and its requirements are not discussed herein.

As to the second element, the PSLRA's approach for pleading scienter sharply deviates from Rule 9(b), which allows plaintiffs to plead the scienter element generally. *Avaya*, 564 F.3d at 253. Under the PSLRA, the court must evaluate whether all the facts in the complaint as alleged, taken collectively, give rise to a "strong inference of scienter" – not whether any individual allegation viewed in isolation meets that standard. *Tellabs*, 551 U.S. at 323. In determining whether the pleaded facts give rise to a strong inference of scienter, the court must "take into account plausible opposing inferences." *Id.* This involves a comparative inquiry that evaluates how likely one conclusion is as compared to others, in light of the pleaded facts. *Id.* Thus, the court must consider plausible, nonculpable explanations for the defendant's conduct as well as inferences favoring the plaintiff. *Id.* at 324. Although the inference that the defendant acted with scienter need not be irrefutable, the inference must be more than merely "reasonable" or "permissible." *Id.* A complaint will survive only if a reasonable person would "deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

III. ANALYSIS

A. Section 10(b) and Rule 10b-5

In Count One, Plaintiff alleges that Defendants violated Section 10(b) and Rule 10b-5. The Third Circuit described such a claim in the following terms:

> Section 10(b) of the Exchange Act prohibits the "use or employ[ment], in connection with the purchase or sale of any security . . . [, of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b). SEC Rule 10b–5 implements this provision by making it unlawful to, among other things, "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5(b). The Supreme Court has

> implied a private cause of action from the text and purpose of [S]ection 10(b). *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 36-37 (2011).

City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 167 (3d Cir. 2014).

Accordingly, to state a securities fraud claim pursuant to Section 10(b) and Rule 10b-5, a plaintiff "must allege (1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation." *Id.* at 167. As to the first element, a plaintiff must "identify a false representation of material fact or omission that makes a disclosed statement materially misleading." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1419 (3d Cir. 1997)). "[A] fact or omission is material only if 'there is a substantial likelihood that it would have been viewed by the reasonable investor as having significantly altered the "total mix" of information' available to the investor." *Id.* (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231-232 (1988)). In other words, courts must "examine statements in the full context of the documents which they are a part" and not engage in a "selective reading" of the statements. *Pfizer, Inc.*, 754 F.3d at 168-69 (citing *Burlington Coat Factory*, 114 F.3d at 1426; *Tellabs*, 551 U.S. at 322).

As discussed, Plaintiff's allegations of securities fraud involve statements that Defendants made about the three I&I pipeline drugs. Because the alleged misrepresentations and omissions are different for each drug, the Court addresses them separately below.

One issue, however, pertains to all three products. To establish securities fraud with respect to each product, Plaintiff relies heavily on information from confidential sources, identified throughout the SAC as "FEs". The FEs are former Celgene employees, consultants and scientists. The Third Circuit has indicated how such allegations must be viewed in light of the PSLRA:

> In our view, the case law interpreting the Supreme Court's *Tellabs* opinion confirms the position we took in [*Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 146 (3d Cir. 2004)]. The PSLRA imposes a particularity requirement on all allegations, whether they are offered in support of a statement's falsity or of a defendant's scienter. 15 U.S.C. § 78u–4(b)(1), (b)(2). In the case of confidential witness allegations, we apply that requirement by evaluating the "detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." *Chubb,* 394 F.3d at 147. If anonymous source allegations are found wanting with respect to these criteria, then we must discount them steeply. This is consistent with *Tellabs*'s teaching that "omissions and ambiguities count against inferring scienter" under the PSLRA's particularity requirements. *Tellabs,* [551 U.S. at 325]. If, on the other hand, a complaint's confidential witness allegations are adequately particularized, we will not dismiss them simply on account of their anonymity. In short, *Chubb* remains good law.

Avaya, 564 F.3d at 263 (footnote omitted). As a whole, Plaintiff provides sufficient information as to the FEs' basis of knowledge, details provided, reliability, corroboration, coherence, and plausibility. The specific role of each FE is provided along with each FE's relevant work dates. In addition, the FEs provide specific factual allegations. As a result, for pleading purposes, the Court generally finds that the FEs' information is sufficient to support a properly-pled complaint. To the extent that allegations from an FE are not appropriately corroborated or lack reliability, the Court will address the specific allegations below.

1. Material Misstatements and Omissions

i. GED-0301

Defendants argue that Plaintiff fails to sufficiently plead any material misrepresentation or omission as to GED-0301. Def. Br. at 15-18. Plaintiff's overall theory with respect to GED-0301 appears to be that Celgene's statements regarding the potential for GED-0301 were not supported by the clinical study results. Plaintiff argues that the "crux" of its claim is that

Defendants "portrayed the results of the clinical trials in an unduly optimistic light." Plf. Opp. at 37 (quoting *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1019 (S.D. Cal. 2005)). But the cases Plaintiff cites in support of this argument are all distinguishable. In each, the court determined that the defendants made material misstatements because defendants were not being fully candid with non-public information. *See, e.g.*, *SEB Inv. Mgmt. AB v. Endo Int'l, PLC*, 351 F. Supp. 3d 874, 900 (E.D. Pa. 2018) (concluding that favorable statement of study results was misleading because "it failed to disclose the countervailing evidence"); *Frater v. Hemisphere Biopharma, Inc.*, 996 F. Supp. 2d 335, 346 (E.D. Pa. 2014) (explaining that stated conclusions would be misleading if they were "the product of statistically unsound analyses of empirically defective trials"); *In re Merck & Co., Inc. Sec., Derivative, & ERISA Litig.*, No. 05-1151, 2011 WL 344199, at *9 (D.N.J. Aug. 8, 2011) (stating that statements were misleading in light of information that was not publicly disclosed); *In re Cell Pathways Inc. Sec. Litig.*, No. 99-725, 2000 WL 805221, at *9 (E.D. Pa. June 20, 2000) (concluding that positive statements about a study were misleading where defendants privately knew of flaws).

Here, Plaintiff identifies shortcomings for the clinical studies, namely the lack of endoscopic data for the Phase II trial and the lack of a placebo control group for the Phase Ib study. Critically, however, this information was publicly disclosed and acknowledged by Celgene. SAC ¶¶ 137-39, 159. Thus, Plaintiff's claims as to GED-0301 are more akin to the claims in *In re Sanofi Securities Litigation*, 87 F. Supp. 3d 510 (S.D.N.Y. 2015). Plaintiffs in *Sanofi* alleged that the defendants' positive statements about Phase III study results were actionable because the defendants failed to disclose certain feedback from the FDA, including that the FDA had reservations about the drug at issue because the clinical trials were single-blind studies. Although the defendants conceded that they did not disclose the FDA feedback, the *Sanofi* court determined

that the defendants' statements were not actionable because the FDA's preference for double-blind studies in general was public knowledge and the fact that the relevant clinical trials used a single-blind design was "well known." *Id.* at 539-40. "Given this publicly available information, a reasonable investor had reason to know that the design of the Lemtrada clinical trials fell short of the FDA's gold standard." *Id.*; *see also In re Sanofi-Aventis Sec. Litig.*, No. 07-10279, 2009 WL 3094957, at *5 (S.D.N.Y. Sept. 25, 2009) ("In fact, plaintiffs' allegations unequivocally demonstrate that accurate rimonabant study data was made available to the public through Sanofi's press releases, S.E.C. filing, and various medical publications.").

In this instance, however, the landscape for potential actionable statements changed after the Phase Ib study data was released in September 2016. Sometime after this point, Plaintiff alleges that internally, Celgene "had effectively given up on GED-0301" despite the fact that it continued to move forward with the Phase III trial. SAC ¶ 187. If in fact Celgene had given up on GED-0301 internally but continued to represent otherwise to investors, the continued representations could constitute material misrepresentations. These allegations are more akin to *Endo*, *Frater*, and the other cases relied upon by Plaintiff.

Plaintiff's allegations, however, lack sufficient factual support. Plaintiff indicates that the clinical trial "enrolled 701 patients across 538 study locations, and was designed to test GED-0301 compared to placebo for a period of 52 weeks, using both clinical and endoscopic measure of remission in response." *Id.* ¶ 184. At the outset, it is not plausible (absent specific contrary evidence) to believe that Celgene would continue with this large-scale, expensive Phase III trial merely for the sake of appearances.

As evidence of Celgene's internal decision to scrap GED-0301, Plaintiff's key allegation appears to be that GED-0301 was not discussed in quarterly review meetings between

approximately September 2016 and when the Phase III trial was stopped in October 2017. Plaintiff also relies on circumstantial information from confidential witnesses who learned of the "fact" that GED-0301 was about to be scrapped from other employees. For example, FE 4's knowledge comes from a non-party employee who FE 4 "believes" would have access to the relevant data. SAC ¶ 183. Moreover, FE 6 learned from another employee that during a meeting, which FE 6 did not attend, the participants discussed the fact that the Phase III trial would not be successful. *Id.* ¶ 194. Moreover, Plaintiff fails to establish that any Defendant was even aware of this alleged decision to scrap GED-0301.

Finally, Plaintiff also provides information which undercuts its position. Specifically, when Celgene announced on October 19, 2017 that it was discontinuing the Phase III trial, Celgene also indicated that it was doing so in accordance with the recommendation of the "Data Monitoring Committee ('DMC'), which assessed overall benefit/risk during an interim futility analysis." *Id.* ¶ 200. Plaintiff explains that a DMC "is an independent committee established as part of large Phase III trials and which is typically comprised of clinicians with expertise in the relevant field being studied, and at least one biostatistician knowledgeable about statistical methods for clinical trials." *Id.* ¶ 200 n. 10. Plaintiff adds that "DMCs are often given access to unblinded study data in order to assess the safety and futility of completing a Phase III trial." *Id.* Thus, Defendants' explanation – that it was relying on a recent DMC recommendation when deciding to stop GED-0301's Phase III trial – is perfectly legitimate. While Plaintiff has suspicions that Defendants had access to confidential information as to the clinical trial earlier, it must provide more sufficient allegations to properly supports its claims.

Plaintiff must provide more concrete information as to Celgene's purported decision to abandon GED-0301 in order to state a claim.[19] Accordingly, Defendants' motion to dismiss is granted as to the allegations about GED-0301.[20]

ii. Otezla

Plaintiff alleges that Defendants made misrepresentations and omissions as to Celgene's ability to meet its 2017 Otezla sales projections. As for the alleged omission, Plaintiff argues that Defendants are liable for material omissions because Defendants failed to "disclose the true cause of the decline in sales." *Id.* ¶ 253; Plf. Opp. at 58-59. Specifically, Plaintiff alleges that Defendants failed to disclose material facts that undermined the 2017 Otezla sales projection as discussed above. *Id.* ¶ 415. A duty to disclose within the context of securities fraud may arise "when there is insider trading, a statute requiring disclosure, or an inaccurate or misleading prior disclosure." *Oran v. Stafford*, 226 F.3d 275, 285-86 (3d Cir. 2000). But "[a]bsent a duty to disclose, silence is not fraudulent or 'misleading under Rule 10b-5.'" *United States v. Schiff*, 602 F.3d 152, 162 (3d Cir. 2010) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988)). In this instance, Plaintiff relies on the third category, alleging that "by putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the fact that

[19] The Court does not need to discuss scienter in light of the conclusion that Plaintiff fails to plead any actionable misrepresentations or omissions. The Court notes, however, that Plaintiff's meager support for its GED-0301 allegations fails to counter the fact that Celgene continued with the Phase III trial even after it purportedly scrapped GED-0301. Thus as pled, the Court finds Plaintiff's scienter allegations implausible. *See, e.g. Pfizer, Inc.*, 754 F.3d at 170 ("Moreover, the initiation of Phase 3 cost millions of dollars and required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure.").

[20] The Court is not ruling, one way or the other, that the GED-0301 allegations are irrelevant for other purposes, such as proving motive. For example, Plaintiff may argue that even if it cannot plausibly state a securities fraud claim based on GED-0301, the failure of the clinical trials put additional pressure on Defendants concerning the other two products at issue.

Celgene was not positioned to meet the 2017 guidance." SAC ¶ 396. Defendants fail to meaningfully address Plaintiff's allegations with respect to omissions regarding the 2017 Otezla sales projection. Accordingly, the Court gives Plaintiff the benefit of the doubt and presumes that Plaintiff establishes actionable omissions with respect to Otezla. The Court now turns its attention to Defendants' specific statements.

a. Forward-Looking Statements

Defendants argue that most of their allegedly misleading statements and omissions about Otezla are protected by the PSLRA Safe Harbor for forward-looking statements. The PSLRA Safe Harbor "immunizes from liability any forward-looking statement, provided that: the statement is identified as such and accompanied by meaningful cautionary language; or is immaterial; or the plaintiff fails to show the statement was made with actual knowledge of its falsehood." *Avaya*, 564 F.3d at 254 (citing 15 U.S.C. § 78u-5(c)). A statement is "forward-looking" if it contains a "projection of revenues, income [], earnings [] per share, capital expenditures, dividends, capital structure, or other financial items," or statements of "future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management." *Id.* at 255 (citing 15 U.S.C. § 78u–5(i)(1)(A)–(C)). In addition, the Safe Harbor applies to material misstatements and omissions. 15 U.S.C. § 78u-5(c).

Most of the statements or omissions at issue here involve Defendants' representations that Celgene was "on track" to meet its 2017 projections for Otezla. *See, e.g.*, SAC ¶¶ 382, 386. Statements that a company is "on track" to reach a target and why the projection is attainable may constitute forward-looking statements. *Avaya*, 564 F.3d at 255-56. Yet, the "on track" comment pertains to Celgene's current position vis-à-vis its future objectives. As a result, the statement is more akin to a mixed present/future statement. With respect to such mixed statements, the

component of the statement that refers to the present is not protected by the Safe Harbor. But when the present-tense statement cannot "meaningfully be distinguished from the future projection of which they are a part," the statement as a whole can be considered forward looking. *Id.* at 255.

Other statements made at the same time as the "on track" comments were not forward looking. In an April 27, 2017 press release, Celgene indicated that it was on track for its 2017 Otezla target but also explained why the Otezla numbers were down in the first quarter. *Id.* ¶ 405 (explaining that the overall market volume of Otezla prescriptions was lower but that the Otezla market share grew, and that net sales were impacted by gross-to-net adjustments related to contracts with several large payers). These explanatory statements about first quarter results are not forward looking—they are comments on something that already occurred. This is clear from the fact that these statements appeared in the press release in a section captioned "First Quarter 2017 Financial Highlights." Decl. of Lawrence S. Lustberg ("Lustberg Decl."), Ex. 43 at 1. Moreover, because they appear in a separate section from the discussion of the 2017 projection, the statements can be distinguished.

Celgene also hosted a conference call on April 27, 2017 during which Kellogg discussed Otezla's first quarter sales miss. *Id.* ¶ 406. On the same call, Curran also discussed first quarter financials, such as "if we look at the underlying dynamics of the business, they're exceptionally strong." *Id.* ¶ 409. Again, these are not forward-looking discussions. Thus, they are not protected by the Safe Harbor. Finally, Alles' statements on May 31, 2017 about Otezla being a "bona fide blockbuster," that Celgene is launching Otezla in Europe and Japan, and that prescription volume has grown, *id.* ¶ 411, are also not forward looking as the statements discuss events occurring when the statements were made.

To fall within the Safe Harbor, Defendants must have included "meaningful cautionary language" that is "extensive and specific." *Avaya*, 564 F.3d at 254, 256 (internal quotations omitted). "To suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions in the prospectus which the plaintiffs challenge." *Id.* (quoting *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 243 n.3 (3d Cir. 2004)). A vague or boilerplate warning that "merely warns the reader that the investment has risks" will not suffice. *Id.* at 256. Finally, "[c]autionary statements disclosed in SEC filings may be incorporated by reference; they 'do not have to be in the same document as the forward-looking statements.'" *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 282 (3d Cir. 2010) (quoting *In re Merck & Co. Sec. Litig.*, 432 F.3d 261, 273 n.11 (3d Cir. 2005)). Oral forward-looking statements must also be accompanied with a cautionary statement or appropriate reference to a written cautionary statement. *In re Anadigics, Inc., Sec. Litig.*, No. 08-5572, 2011 WL 4594845, at *18 (D.N.J. Sept. 30, 2011).

Celgene's 10-Ks each include a detailed explanation of multiple risk factors. In Celgene's 2015 10-K, for example, Celgene stated that the success of Celgene's primary products, including Otezla,

> depends on acceptance by regulators, key opinion leaders, physicians, and patients as effective drugs with certain advantages over other therapies. A number of factors, as discussed in greater detail below, may adversely impact the degree of acceptance of these products, including their efficacy, safety, price and benefits over competing products, as well as the reimbursement policies of third-party payers, such as government and private insurance plans.

Lustberg Decl., Ex. 23 at 17. Celgene further noted that its product sales

> depend, in large part, on the conditions under which our products are paid for by health maintenance, managed care, pharmacy benefit and similar health care management organizations (HCMOs), or

> reimbursed by government health administration authorities, private health coverage insurers and other third-party payers.

Id. at 19. Celgene also stated that "HCMO-implemented restrictions imposed upon our products can significantly impact drug usage in the HCMO patient population, and consequently our revenues." *Id.* Finally, Celgene discussed barriers to entry outside of the United States. *Id.*

Courts have determined that similar cautionary language is extensive and specific enough to satisfy the Safe Harbor. *In re Aetna*, 617 F.3d at 282-83. Moreover, these specific and detailed discussions of potential risks address the prime concerns outlined by Plaintiff in the SAC; namely, the step-edit requirements, competition from established and more effective products, and barriers to entry in markets outside of the United States. Celgene also incorporated its detailed warnings in its other filings with the SEC and in multiple investor presentations. As a result, the majority of Defendants' forward-looking statements contained appropriate cautionary language. Thus, these statements (SAC ¶¶ 381, 384, 386-90, 392-93, 395-96, 398, 400, 401-02, 405-09, 412-13) are protected by the PSLRA Safe Harbor. But as pled, certain of Defendants' oral forward-looking statements did not contain meaningful cautionary language.[21] SAC ¶¶ 382, 391, 397, 411. For example, during the January 12, 2015 conference, Hugin stated only that "the presentation, hopefully, does have forward-looking statements, and results may or may not be as I discussed here today." Lustberg Decl., Ex. 49. This cautionary statement is not substantive nor did Hugin

[21] With respect to the statements pled in ¶¶ 391, 397 and 411 of the SAC, Plaintiff did not plead that there was meaningful cautionary language in the SAC nor did Defendants include a transcript from the presentation or copy of the deck used during the presentations during which each statement was made. As a result, the Court is unable to ascertain whether Defendants provided sufficient cautionary language. Given the fact that at the motion to dismiss stage, the Court must construe the SAC in Plaintiff's favor, the Court will assume that there was not appropriate cautionary language.

reference other cautionary statements. Accordingly, these statements that did not incorporate Celgene's 10-K cautionary language are not protected by the Safe Harbor.

To the extent that any forward-looking statements are not protected by meaningful cautionary language, Defendants maintain that no statements were made with actual knowledge of their falsity. Def. Br. at 46. While Plaintiff certainly pleads facts to demonstrate that certain Celgene employees doubted whether the 2017 projections were attainable from the beginning of the Class Period, Plaintiff does not establish that any Defendant knew that the 2017 projection was unattainable until, at the earliest, July 2016. Specifically, Smith and Curran were "expressly warned" in at least one meeting during the third quarter of 2016 "that the forecasted Otezla sales for 2017 were not attainable." SAC ¶ 236. Therefore, the forward-looking statements that occurred prior to this time frame were not made with actual knowledge of falsity. *Id.* ¶¶ 382, 391. Accordingly, these statements are not actionable as they are protected by the Safe Harbor. The only remaining forward-looking statement was made by Alles' at a May 31, 2017 conference. *Id.* ¶ 411. Plaintiff, however, fails to allege that Alles was told that the 2017 numbers were not possible. Thus, this statement is also not actionable.

b. Non-Forward-Looking Statements

Turning to the non-forward looking statements, SAC ¶¶ 397, 405, 406, 409, 411, Plaintiff fails to demonstrate that they all constitute misrepresentations or omissions. "Factual recitations of past earnings, so long as they are accurate, do not create liability under Section 10(b)." *Galati v. Commerce Bancorp, Inc.*, 220 F. App'x 97, 102 (3d Cir. 2007) (quoting *In re Advanta*, 180 F.3d at 538). As a result, the discussion of Otezla's first quarter sales in the April 2017 press release, SAC ¶ 405, is not actionable. And with respect to Kellogg's statement on the April 27, 2017 conference call, *id.* ¶ 406, Kellogg was not discussing the 2017 Otezla projections, he was

discussing Celgene's first quarter financials. *See* Lustberg Decl., Ex. 44 at 3. Thus, this statement is also not actionable.

The next statement at issue was made by Curran during the April 27 conference call. Curran's identified statement was a response to a question and constitutes his opinion on whether Otezla sales will bounce back. SAC ¶ 409. "Opinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." *Pfizer, Inc.*, 754 F.3d at 170. Plaintiff pleads sufficient facts to suggest that Curran's opinion lacked a reasonable basis and that Curran did not honestly believe it. As discussed, Curran was explicitly warned by the third quarter of 2016 that Celgene was not going to hit its 2017 projection. In fact, Plaintiff alleges that Curran and Smith told the forecasting team to change the internal forecasts to conceal the lack of sales growth.[22] SAC ¶¶ 237-38, 241. This statement, therefore, is actionable. This is also the case for Alles' statement on May 31, 2017. *Id.* ¶ 411.

Defendants argue that all of the non-forward-looking statements constitute puffery. Def. Br. at 51. Puffery amounts to "vague and non-specific expressions of corporate optimism on which reasonable investors would not have relied." *In re Aetna*, 617 F.3d at 284. Accordingly, a defendant cannot be liable for securities fraud for statements of puffery. *Id.* Only Smith's statement on September 12, 2016, *id.* ¶ 397, constitutes puffery. In response to an investor's question about the 2020 sales projections, Smith used words such as "I feel really great" and "I am just excited". *Id.* Smith also failed to discuss any detailed financial numbers when responding to the question.

[22] Although Plaintiff's allegations with respect to Otezla are also based largely on allegations from FEs, Plaintiff's allegations are corroborated by multiple FEs, actual sales numbers, and Plaintiff alleges that certain Individual Defendants were explicitly told that the 2017 projections were problematic. Thus, the Court finds these allegations more credible than the FEs allegations with respect to GED-0301.

In sum, Plaintiff alleges actionable statements from Curran and Alles.

iii. Ozanimod

Defendants argue that Plaintiff fails to identify a false or misleading statement as to Ozanimod. Def. Br. at 58. Plaintiff counters that Defendants' failure to disclose Celgene's discovery of the Metabolite and need for further Phase I testing are actionable half-truths. Plf. Opp. at 12-13. Plaintiff continues that because Defendants chose to speak on the subject of the clinical study data results, Defendants were obligated to speak truthfully and completely on the subject to not mislead investors. *Id.*

This issue was addressed in *SEB Investment Management AB v. Endo International, PLC*, 351 F. Supp. 3d 874, 900 (E.D. Pa. 2018). That case involved statements regarding the safety of Endo's reformulated opioid pain medication and whether Endo could obtain FDA approval for the reformulated drug. Specifically, Endo made changes that made it more difficult to crush the pills in order to decrease the risk of opioid abuse. *Id.* at 885-86. In discussing the reformulated drug, certain defendants represented that there was sufficient clinical data to support a determination that the drug was now safer and less prone to abuse. At the time, however, these defendants knew that the data demonstrated an increase in intravenous drug abuse. *Id.* at 898-900. The *Endo* court determined that these statements constituted misrepresentations. The court explained that while the "non-disclosure of material information is actionable only if there is an affirmative duty to disclose," a "duty arises when disclosure is necessary to make statements not misleading." *Id.* at 897. Moreover, the court in *Endo* continued, "once a company has chosen to speak on an issue, even one it had no independent obligation to discuss, it cannot omit material facts related to that issue." *Id.* As a result, the judge in *Endo* determined that statements regarding the favorable data

were "affirmative statement[s] that painted a favorable picture without including the details that would have presented a complete and less favorable one." *Id.* at 900.

Here, Plaintiff has plausibly pled allegations as to certain Defendants concerning Ozanimod. Celgene repeatedly indicated that it would submit the NDA for Ozanimod by the end of 2017, and Celgene did in fact do so. However, in light of Celgene's discovery of the Metabolite and the FDA's guidance concerning metabolites as well as specific alleged facts, Celgene's disclosure as to the NDA submission was materially incomplete and misleading. To make the public disclosures concerning the NDA legally accurate, Celgene was required to also disclose meaningful information as to the Metabolite vis-à-vis the NDA.

Plaintiff alleges that FDA guidance indicates that differences in drug metabolism between animals and humans should be identified "as early as possible during the drug development process" and that the late discovery of disproportionate drug metabolites may cause development and marketing delays. SAC ¶ 286. Moreover, if a metabolite is discovered that accounts for more than 10% of total drug related exposure and the exposure in humans is higher than in animal studies, the FDA guidance states that additional testing is required. *Id.* ¶ 289; *see also* Safety Testing of Drug Metabolites Guidance for the Industry, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-testing-drug-metabolites (Nov. 2016). In addition, the FDA requires that NDAs include "[a] section describing the human pharmacokinetic data and human bioavailability data." SAC ¶ 283 (quoting 21 C.F.R. § 314.50(d)(3)). Thus, Plaintiff sufficiently alleges that applicable FDA guidance put Celgene on notice that Celgene faced significant hurdles with the Ozanimod NDA without appropriate testing and information concerning the Metabolite.

This general FDA guidance is buttressed by factual allegations from FEs. For example, FE 21 discussed the Metabolite discovery with his manager, who others have identified as Martin, and that senior leadership at Celgene knew of the discovery. *Id.* ¶ 299. FE 5 explained that Tran confirmed the need for additional testing at a meeting in March or April of 2017, and that Martin was also present at this meeting. *Id.* ¶¶ 304-05. In addition, when Tran published a paper in August 2017 concerning certain metabolites that were discovered as to Ozanimod, he omitted any reference to the Metabolite. Plaintiff further pleads that the FDA informed Celgene that study results for the Metabolite testing must be included in the Ozanimod NDA.[23] *Id.* ¶¶ 316-317. Ultimately, Celgene received an RTF from the FDA. An RTF is only issued when an NDA has "clear and obvious deficiencies." *Id.* ¶ 324.

Thus, FDA guidance and employees at Celgene, including Defendants Tran and Martin, knew that additional testing was required in light of the Metabolite discovery and that the NDA was not going to approve the NDA without the necessary Metabolite testing results. These allegations make some of Defendants' non-forward-looking statements regarding the positive clinical data actionable.

Celgene apparently learned of the Metabolite around November 21, 2016, when the Mass Balance Study for the Phase I trial was completed. On January 9, 2017 Alles stated that Celgene was waiting for Phase III data, and "contingent on that, we will file an NDA for Ozanimod in multiple sclerosis by the end of the year." *Id.* ¶ 417. Similarly, on March 15, 2017, Flanigan said

[23] The allegations that pertain to Celgene's purported meeting were provided by FE 22. The Court, however, does not give great weight to these allegations because FE 22 was a contractor with Receptos for only a matter of months. In addition, Plaintiff fails to explain how FE 22 learned this information, which Individual Defendants were aware of the FDA's requirement, who attended the meeting or other substantiating information. But even without this information, Plaintiff sufficiently plead actionable omissions with respect to Ozanimod.

that if the Phase III data sets were consistent, "then we will package all this into an NDA and submit it to the FDA by the end of the year." *Id.* ¶ 429. Although these are forward-looking statements, it does not appear that they were accompanied by meaningful cautionary language. Plaintiff, however, fails to sufficiently plead that Alles or Flanigan knew these statements were false at the time.[24] Although Celgene had discovered the Metabolite at this time, it is not clear whether Alles or Flanigan were aware that additional testing was required. *See id.* ¶ 304 (stating that Tran explained that additional testing was required in March *or April* of 2017). These statements, therefore, are protected by the Safe Harbor.

But on May 31, 2017, Alles discussed Ozanimod's Phase III study results at a conference. Alles stated that "the results of the 2 Phase II trials separately and together for relapsing MS *put the product at a profile that's better than the base case we had when we did the deal to acquire the asset.*" SAC ¶ 438; *see also id.* ¶¶ 449, 457. When these statements were made, Celgene had discovered the Metabolite, knew that additional testing was required, and that the Metabolite compromised the safety and efficacy profile of Ozanimod. In short, without the necessary Metabolite testing, the contemplated NDA was dead on arrival. The fact that Defendants told investors about the positive clinical study results but failed to disclose the Metabolite discovery was misleading. Because Defendants chose to make statements regarding the clinical data, they were required to fully and truthfully discuss the results.

Defendants counter that because the statements at issue only pertain to the Phase III study results, they were only required to be truthful with respect to the Phase III clinical study data. Def. Reply at 25-26. The Court disagrees because the statements were made in connection with

[24] The Court recognizes that the lack of sufficient allegations concerning a Defendant's knowledge could also be disposed of in the scienter section below. However, because the parties address the issue in terms of misstatement or omission, the Court does so as well.

submitting the NDA by the end of the year. *See, e.g.*, SAC ¶ 449 (indicating that Curran stated on October 26, 2017 that the "program remains on track for regulatory submission, beginning with the U.S. by year-end"); *id.* ¶ 455 (alleging that Martin said on October 28, 2017 that Celgene was getting ready to file the NDA by the end of the year); *id.* ¶ 456 (claiming that Curran represented on October 28, 2017 that Celgene was looking forward to filing the NDA by the end of 2017). In addition, on October 28, 2017, Smith did refer to the Phase III data but he did not limit his comments to that information. Instead, Smith essentially referred to all data that Celgene had acquired concerning Ozanimod. *Id.* ¶ 457.

Defendants' non-forward-looking statements about the NDA submission in December 2017 are also actionable. *See* SAC ¶¶ 463, 465. In January and February of 2018, Celgene issued press releases stating that it submitted the NDA for Ozanimod. Moreover, Celgene's 2017 10-K (which was submitted on February 7, 2018), listed the status of its Ozanimod development as in "Regulatory Submission" for RMS, in Phase III for UC, and in Phase II for CD. While Celgene truthfully stated that it submitted the NDA, this representation was misleading because of Plaintiff's allegations that Celgene knowingly submitted a facially deficient NDA that failed to contain information specifically requested by the FDA. By telling investors that it submitted the NDA, Defendants were required to disclose the known shortcomings of Celgene's submission. *See In re Bristol-Myers Squibb Sec. Litig.*, No. 00-1990, 2005 WL 2007004, at *23 (D.N.J. Aug. 17, 2005) ("Thus, even objectively true statements can be actionable if Plaintiff can sustain its allegations that Defendants omitted material information that rendered a facially true statement false or misleading.").

In sum, Plaintiff pleads that Alles, Kellogg, Curran, Martin and Smith made actionable statements about Ozanimod.

2. Scienter

"Scienter is a mental state embracing intent to deceive, manipulate, or defraud, and requires a knowing or reckless state of mind."[25] *Avaya*, 564 F.3d at 252 (internal citations and quotations omitted) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 n. 12 (1976) and citing *Advanta*, 180 F.3d at 534-35). The PSLRA scienter standard "requires plaintiffs to allege facts giving rise to a 'strong inference' of 'either reckless or conscious behavior.'" *Id.* at 267 (quoting *Advanta*, 180 F.3d at 534-35). A reckless statement is one "involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Id.* at 267 n. 42 (citing *Advanta*, 180 F.3d at 535). "'[C]laims essentially grounded on corporate mismanagement' do not adequately plead recklessness." *Id.* (citing *Advanta*, 180 F.3d at 540).

A "strong inference" of scienter is one that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 267 (quoting *Tellabs*, 551 U.S. at 324). It is more than "merely 'reasonable' or 'permissible.'" *Tellabs*, 551 U.S. at 324. To make this determination, a court must "weigh the plausible nonculpable explanations for the defendant's conduct against the inferences favoring the plaintiff." *Avaya*, 564 F.3d at 267 (quoting *Tellabs*, 551 U.S. at 324) (internal quotations omitted). However, "[t]he inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the 'smoking-gun' genre, or even the most plausible of competing inferences." *Id.* (quoting *Tellabs*, 551 U.S. at 324). "The pertinent question is 'whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not

[25] This standard is distinguishable from the required mental state for forward-looking statements to qualify for the PSLRA Safe Harbor provision, which requires actual knowledge. *See* 15 U.S.C. § 78u-5(c).

whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* at 267-68 (quoting *Tellabs*, 551 U.S. at 323). "Omissions and ambiguities 'count against inferring scienter.'" *Id.* at 268 (quoting *Tellabs*, 551 U.S. at 326). "Motive and an opportunity to commit fraud" are just a factor in this analysis. *Advanta*, 180 F.3d at 534-35. In sum, "[a] complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

In *Avaya*, the shareholder plaintiffs brought a securities fraud action against Avaya, Inc. and its executives for statements about earnings and growth potential. 564 F.3d at 245. Avaya's CFO made statements "repeatedly assur[ing] analysts and investors that although there was pressure in the market, there were no significant changes to the pricing environment." *Id.* at 268. The plaintiffs alleged that the CFO made these statements while "kn[owing] of or recklessly disregard[ing] the fact that competition was forcing unusually large 20% to 40% price discounts that were hurting profit margins." *Id.* On appeal, the Third Circuit addressed whether the complaint sufficiently alleged scienter as to these pressure-pricing statements. *Id.* The *Avaya* court ultimately determined that given the totality of the circumstances, "the culpable explanation of [the CFO]'s March discounting statements is at least as compelling as the nonculpable alternatives." *Id.* at 272. The Third Circuit ruled as follows:

> Taken together, the extent of the alleged discounting, the importance to the "Avaya story" of maintaining margins, the amount by which the second quarter results missed expectations, the proximity of [the CFO]'s statements to the end of the quarter and the release of results, [the CFO]'s position as Chief Financial Officer, and most significantly, the content and context of the statements themselves, give rise to a strong inference that [the CFO] either knew at the time that his statements were false or was reckless in disregarding the obvious risk of misleading the public.

Id.

The allegations here are similar with respect to Otezla and Ozanimod as to the allegations which the Court found were properly pled. As for Otezla, Plaintiff contends that Smith and Curran received warnings from employees that Celgene's 2017 sales projection for Otezla was unattainable in approximately July 2016. Through FEs, Plaintiff provides sufficient circumstantial evidence to suggest that Curran's statement that Celgene was on-track to meet its 2017 goal was, at a minimum, recklessly made. SAC ¶ 409. The temporal proximity of the statement at issue buttresses the Court's conclusion; Curran's statement was made after Otezla failed to meet Company expectations for the first quarter of 2017 and Celgene lowered top end of the 2017 sales goal. *Id.* ¶¶ 244, 253. Thus, the fact that Celgene was under pressure to find a new source of profitability gives rise to a strong inference that Curran was at best, recklessly disregarding the risk of misleading the public as to Celgene's ability to meet the Otezla sales projections.

Defendants argue that Plaintiff's confidential witnesses, through whom Plaintiff establishes that Defendants were ignoring internal warnings about Celgene's inability to meet the 2017 forecast, should be steeply discounted because the FEs "isolated viewpoints are refuted by Otezla's strong sales."[26] Def. Reply at 23. But, in January 2017, Celgene lowered the top end of its projection, SAC ¶ 244, and Otezla's sales declined in the first quarter of 2017, *id.* ¶ 253. This objective evidence demonstrates that the confidential witnesses did not have "isolated views" and that Otezla's sales were not as strong as Defendants led the public to believe.

The other actionable material misrepresentation involving Otezla was made by Alles. SAC ¶ 411. Plaintiff, however, fails to establish that Alles knew that Celgene's 2017 projection was unattainable. Plaintiff appears to rely on the "core operations" doctrine to establish scienter as to

[26] "Strong" sales is disputed by Plaintiff, who claims that the Otezla sales were essentially flat since 2015.

Alles. SAC ¶¶ 509-12. The core operations doctrine provides that when misrepresentations and omissions involve "'core matters' of central importance" to the corporate defendant, "a 'core operations interference' supports scienter." *Avaya*, 564 F.3d at 268. But "a corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013). Rather, there must be "some additional allegations of specific information conveyed to management and related to fraud." *Id.* Here, Plaintiff alleges that Otezla and Ozanimod were critical to replacing revenue when Revlimid lost its patent protection. When Celgene announced the license deal with Nogra for GED-0301, Celgene's presentation to investors explained that it was a "[s]trategic deal" that "meaningfully diversifies portfolio revenue in 2019-2020 time period and beyond." SAC ¶ 113. And when Celgene acquired Receptos, it increased its 2020 revenue guidance for the I&I franchise by more than $1 million, and projected annual Ozanimod sales of up to $6 billion. *Id.* ¶¶ 271, 510. After announcing the Receptos acquisition, Celgene noted that its "I&I pipeline will . . . consist of three high-potential commercialized or late-stage assets: Otezla, GED-0301 and Ozanimod." *Id.* ¶ 511. The alleged importance of Revlimid to Celgene's product portfolio and the fact that Plaintiff pleads more than "general awareness of the day-to-day working" plausibly suggests that Otezla and Ozanimod was a part of Celgene's "core operations." *See In re Allergan Generic Drug Pricing Sec. Litig.*, No. 16-9449, 2019 WL 3562134, at *12 (D.N.J. Aug. 6, 2019) (applying core operations doctrine where alleged misrepresentations addressed three drugs that made up a "substantial portion" of the defendant company's revenues and operations during the class period). While the fact that Otezla and Ozanimod were important products in Celgene's portfolio gives further credence to Plaintiff's allegations, the Court will not infer scienter as to Alles based solely on the core operations doctrine and "without other particularized facts about specific information

conveyed to management." *In re Cognizant Tech. Sols. Corp. Sec. Litig.*, No. 16-6509, 2018 WL 3772675, at *29 (D.N.J. Aug. 8, 2018). But without the core operations doctrine, Plaintiff fails to establish scienter as to Alles.

With respect to Ozanimod, Plaintiff pleads that after Celgene acquired Receptos, Celgene effectively controlled Receptos and oversaw the Ozanimod project. *Id.* ¶ 508(a). After Celgene discovered the Metabolite, Plaintiff pleads that at a minimum Tran and Martin knew by April 2017 of the Metabolite discovery and were aware that additional testing was necessary. FE 21 stated that Celgene's senior leadership was also aware of these facts, and FE 5 recounted that Martin reported to Smith. Given the importance of the product to Celgene, along with Martin's direct reporting responsibility to Smith, Plaintiff establishes a reasonable inference that Smith was also aware of the Metabolite. FE 21 also explained that he and his colleagues believed that if Celgene submitted the NDA without the Metabolite data, Celgene would receive an RFT. FE 21 "confirmed that this was said to his direct management," SAC ¶ 508(b)(vi), who others have confirmed was Martin. Moreover, although Celgene tried to blame Receptos for the RFT, statements made by Ahmed and non-parties strongly suggest that Celgene knew of the deficiencies in the NDA. *See* SAC ¶¶ 337, 338. The Court, therefore, concludes that the fact that Celgene was under pressure to find a new source of profitability gives rise to a strong inference that Smith and Martin were at best, recklessly disregarding the risk of misleading the public as to Celgene's ability to obtain FDA approval for Ozanimod.[27] In addition, Smith and Martin, among others, received a performance award and/or bonus, in part, because the NDA was filed in 2017. These additional facts demonstrate that Smith and Martin also had a personal financial motivation to push for the

[27] Plaintiff also pleads sufficient facts to establish scienter for Tran. Tran, however, did not make any actionable misstatements.

NDA filing to occur 2017. *See Tellabs, Inc.*, 551 U.S. at 325 (explaining that while the absence of a motive allegation is not fatal, "motive can be a relevant consideration, and personal financial gain may weight heavily in favor of a scienter inference").

But Plaintiff fails to sufficiently plead scienter as to Alles, Kellogg and Curran, the remaining Defendants that made actionable misstatements about Ozanimod. As discussed above with respect to Smith's statements about Otezla, Plaintiff fails to establish that Alles, Kellogg and Curran knew about the need for additional testing in light of the Metabolite discovery or the incomplete NDA submission. In addition, without more specific information, the Court will not infer scienter as to these Defendants based solely on the core operations doctrine.

Finally, Plaintiff's attempt to further establish scienter based on certain Defendants' ownership of Celgene stock and the timing of stock sales is unavailing. Plaintiff bases its allegations off of six stock sales from Alles, Curran and Hugin that occurred between 2015 and 2017. SAC ¶ 514. Stock sales "may support an inference of scienter" if they are "unusual in scope or timing." *Avaya, Inc.*, 564 F.3d at 279. Here, five of the six identified sales were made pursuant to 10b5-1 trading plans. *Id.* ¶ 520. The only sale that did not occur pursuant to a trading plan was Hugin's sale on June 22, 2017, approximately four months before Celgene announced that it had lowered its 2017 sales guidance. Although the timing is somewhat suspect, Hugin only sold approximately 4% of his Celgene holdings. Accordingly, these identified stock sales are not enough to give rise to any further inference of scienter. *See Avaya*, 564 F.3d at 279 (concluding that stock sales pursuant to a Rule 10b5-1 plan did not enhance the inference of scienter); *In re Hertz Glob. Holdings Inc.*, 905 F.3d 106, 120 (3d Cir. 2018) (stating that scienter inference was lessened because "the timing of the insider trades is not particularly suspicious," there were only

insider trading allegations against two of the five name individual defendants, and the percentage of stock holdings sold was low).

In sum, Plaintiff establishes scienter only as to Smith, Martin and Curran, which may be imputed to Celgene.[28]

4. Reliance

Plaintiff relies on a fraud-on-the-market theory of reliance. SAC ¶¶ 533-540. With the fraud-on-the-market presumption, "if a market is shown to be efficient, courts may presume that investors who traded securities in that market relied on public, material misrepresentations regarding those securities." *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 568 U.S. 455, 462 (2013). Defendants do not challenge Plaintiff's allegations regarding the fraud-on-the-market presumption. Accordingly, the Court concludes that Plaintiff adequately pleads reliance.

5. Loss Causation & Economic Loss

Defendants also fail to challenge Plaintiff's economic loss or loss causation allegations. As for economic loss, Plaintiff pleads that it purchased stock during the class period and was damaged as a result of the alleged misrepresentations and omissions. SAC ¶ 546.

Loss causation requires "a causal connection between the material misrepresentation and the loss." *McCabe v. Ernst & Young, LLP.*, 494 F.3d 418, 424 (3d Cir. 2007) (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)). Specifically, the "loss causation inquiry asks whether the misrepresentation or omission proximately caused the economic loss." *Id.* at 426

[28] While not raised by any party, the scienter of the individual Defendants who made actionable statements, who are all corporate officers, is imputed to Defendant Celgene. *See Avaya*, 564 F.3d at 251-52 ("Although Shareholders' Complaint focuses on the statements of McGuire and Peterson, liability for these statements, if they were fraudulent, can also be imputed to Avaya because a corporation is liable for statements by employees who have apparent authority to make them.").

(citing *Semerenko v. Cendant Corp.*, 223 F.3d 165, 185-87 (3d Cir. 2000)). Plaintiff here utilizes the "materialization of the risk" approach to demonstrate when a misrepresentation or omission "proximately causes" the economic loss in the context of an undisclosed risk. *Id.* Under the "materialization of the risk" approach, Plaintiff must prove that "the materialization of the undisclosed risk caused the alleged loss." *McCabe*, 494 F.3d at 429 (quoting Dane A. Holbrook, *Measuring & Limiting Recovery Under Rule 10b–5: Optimizing Loss Causation and Damages in Securities Fraud Litigation*, 39 Tex. J. Bus. L. 215, 260-62 (2003)).

Plaintiff pleads that on October 26, 2017, Celgene announced that it lowered its 2017 guidance by more the $250 million overall, and the 2020 I&I projection by over $1 billion because of "dismal" Otezla sales numbers. *Id.* ¶ 264. After this news was announced, the price of Celgene common stock declined more than 16%; from $119.56 per share on October 25, 2017 to $99.99 per share on October 26, 2017. *Id.* ¶ 269. Accordingly, Plaintiff appropriately alleges loss causation with respect to Otezla. As for Ozanimod, after news that Celgene received an RFT from the FDA reached the market, Celgene's common stock fell from $95.78 per share on February 27, 2018 to $87.12 per share on February 28, 2018. *Id.* ¶ 330. Celgene's common stock also fell after news indicating that the Ozanimod NDA would be delayed by one to three years because the need for additional testing was disclosed. The stock fell from $95.78 per share on April 27, 2018 to $87.10 per share on April 30, 2018. *Id.* ¶ 332. Thus, Plaintiff also sufficiently pleads loss causation with respect to Ozanimod.

B. Section 20(a)

In Count Two, Plaintiff asserts claims for control person liability against Alles, Kellogg, Smith, Curran, Hugin and Fouse under Section 20(a) (the "Section 20(a) Defendants"). SAC ¶¶ 547-53. "Section 20(a) of the Exchange Act imposes joint and several liability on any individual

who exercises control over a 'controlled person' who violates Section 10(b)." *Carmack v. Amaya Inc.*, 258 F. Supp. 3d 454, 466 (D.N.J. 2017) (citing 15 U.S.C. § 78t(a); *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 275 (3d Cir. 2005)). The three elements to this claim are: "(1) the defendant controlled another person or entity; (2) the controlled person or entity committed a primary violation of the securities laws; and (3) the defendant was a culpable participant in the fraud." *Id.* (citing *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 286 (3d Cir. 2006)). Thus, "liability under Section 20(a) is contingent upon sufficiently pleading an underlying violation of Section 10(b) by the controlled person." *Id.*

"Culpable participation refers to either knowing and substantial participation in the wrongdoing or inaction with the intent to further the fraud or prevent its discovery." *Id.* (citing *Rochez Bros., Inc. v. Rhoades*, 527 F.2d 880, 890 (3d Cir. 1975)). Thus, "[u]nder the plain language of the statute, plaintiffs must prove not only that one person controlled another person, but also that the 'controlled person' is liable under the [Exchange] Act." *Id.* (quoting *Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 484 (3d Cir. 2013)). "Accordingly, liability under Section 20(a) is contingent upon sufficiently pleading an underlying violation of Section 10(b) by the controlled person." *Id.* Plaintiff sufficiently pleads an underlying Section 10(b) violation with respect to Smith, Curran, Martin and Celgene. Thus, Plaintiffs must establish that Alles, Kellogg, Hugin and Fouse controlled these Defendants and that they were culpable.[29] Plaintiff only provides the conclusory allegation that the Section 20(a) Defendants "each had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company." SAC ¶ 551. Likewise, Plaintiff's opposition makes only a passing reference to

[29] Plaintiff fails to allege that Ahmed, Tran and Callegari made any actionable statements or that they are liable pursuant to § 20(a). While not explicitly addressed, because there is no basis for liability as to these Defendants, they are dismissed as Defendants in this matter.

the issue. This is insufficient to state a Section 20(a) claim. *See Carmack*, 258 F. Supp. 3d at 469. As a result, Count Two is dismissed.

IV. CONCLUSION

In sum, the Court grants in part and denies in part Defendants' motion, D.E. 54, to dismiss Lead Plaintiff's SAC. D.E. 52. With respect to the portions of the SAC that are dismissed, the dismissal is without prejudice. Plaintiff shall have thirty (30) days to file a second amended complaint, which cures the deficiencies noted herein. If Plaintiff does not file an amended pleading, the dismissed claims will be dismissed with prejudice. An appropriate Order accompanies this Opinion.

Dated: December 19, 2019

John Michael Vazquez, U.S.D.J.